Bayer Corporation vs. Union of India and Bayer Intellectual Property GMBH & Anr. vs. Alembic Pharmaceuticals Ltd.

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The Hon'ble Division Bench comprising Hon'ble Mr. Justice Ravindra Bhat and Hon'ble Mr. Justice Sanjeev Sachdeva vide order dated 22nd April 2019 disposed of the appeals arising from the suit as well as writ petition and held that:

1. It cannot be held that the Parliament intended to per se exclude "exports" from the sweep and width of the term "sale" in Section 107A. "Exports" is used in different contexts in Section 84, 90 and 92A, which govern Compulsory licensing (paragraphs 82 to 84)
2. Section 107A is not made subject to other provisions of the Act – on the other hand, Section 48, which talks of the rights of the patent holder is subject to other provisions of the Act that includes Section 107A. Section 107A is not an exception. It is an independent provision, a special provision that deals with the rights of the patented invention for research purposes. (paragraphs 88 and 89)
3. Once it is held that patented inventions can be sold for the purpose of carrying on research which fulfils the regulatory requirements of India, there cannot be any bar or an interpretation narrowing scope of such sale. What is important is the purpose of the sale. (Para 91)
4. The natural interpretation of the expression "use" is all its senses. National regimes might well insist that such research and experimentation in regard to those aspects be either entirely or at least in part be carried on their territory. In this context, therefore, it is held that the expressions used in Section 107A has to be given a wide import. (paras 91 and 92)
5. The broad nature of the provision – which enables development and research of the product and information related hereto, on fulfilling the regulatory or other legal requirements of India, and other countries – cannot be construed narrowly as to permit development and research of the product only in India. (para 94)
6. The conduct and action of the individual or entity making, using, constructing or selling the patented product or invention and the purpose for which it sought to be used (i.e. end use and that it should not be commercial) would be important and decisive whether the exporting or purchasing entity intends to use the patented product for commercial purposes. (para 105)
7. The Court is cognizant of the fact that export of patented invention can be potentially troublesome to the patent owner; an unregulated export activity can result in exploitation of the Bolar exemption beyond what can be considered "reasonably" related to obtaining approval under laws India or another country. (para 106)
8. There cannot be an iron clad rule or bright line as to what acts are reasonably related to the use or sale of the product with the object of using the developed information to satisfy

regulations. Each case merits an analysis of the evidence, the proof regarding the regulatory concerns is to be based on it. (paras 108, 109)

9. The approach of the learned Single Judge in permitting export, without any inquiry and holding that export of 100 or 2000 tablets constituted reasonable use, in this case cannot be countenanced. (Para 111)
10. The Court is of the opinion that the inquiry and adjudication in such cases would be in regard to the following:

- The patent granted
- The nature of the product sought to exported;
- The details of the party importing the product;
- The quantity sought to be exported;
- Other particulars with respect to the end use of the product;
- All particulars regarding the relevant regulations, including quantities of the products.

11. If regulations are in the language of that country, an authentic English translation to be provided to facilitate a speedy resolution; 12. If regulations are in the language of that country, an authentic English translation to be provided to facilitate a speedy resolution; 13. Appropriate interim order, including undertaking on affidavit to compensate the plaintiff, in the event the suit were to be decreed and the extent of monetary compensation. 14. If necessary, verification through the Indian mission (and its trade division) abroad regarding the authentication of the third party and/or its facilities abroad. 15. It is held by the court that the exporter is not involved in sale or export of any patented product, but a generic article unprotected by patent law, when denying relief, suitable restitutionary relief should be awarded to the Defendant in monetary terms, to preclude litigation that prevents trade or competition. (para 111) 16. Sale, use, construction of patented products in terms of S. 107A for purposes both within the country and abroad is authorized and legal provided the seller ensures that the end use and purpose of sale / export is reasonably related to research and development of information in compliance with regulations or laws of India (or of importing country), for its submission in accordance with such laws. [para 119(a)] 17. A dispute about such a sale, is properly the subject matter of a civil suit in which the full range of reliefs available in law can be granted having regard to the circumstances and evidence led. The Court trying the suit would suitably take into account factors to be examined (as elaborated) and other relevant factors. [para 119 (b and c)] Team Anand and Anand: Pravin Anand, Dhruv Anand and Udita M Patro.